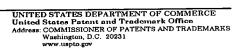


# UNITED STATES PATENT AND TRADEMARK OFFICE



APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
. 09/103,355	06/23/1998	PETER J. KUSHNER	2307O-080510	2899
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LAW OFFICES OF JONATHAN ALAN QUINE			EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.

09/103,355

Applicant(s)

Kushner et al.

## Office Action Summary

Examiner

Michael Pak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). **Status** 1) Responsive to communication(s) filed on *Dec 26, 2001* 2b) X This action is non-final. 2a) This action is FINAL. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213. Disposition of Claims is/are pending in the application. 4) X Claim(s) 1-13 4a) Of the above, claim(s) \_\_\_\_\_\_\_ is/are withdrawn from consideration. 5) Claim(s) is/are rejected. 6) 🗓 Claim(s) 1-13 \_\_\_\_\_is/are objected to. 7) Claim(s) \_\_\_\_\_\_ 8) Claims \_\_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. is/are objected to by the Examiner. 10) ☐ The drawing(s) filed on 11) ☐ The proposed drawing correction filed on \_\_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved. 12) The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. § 119 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). a)  $\square$  All b)  $\square$  Some\* c)  $\square$  None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \*See the attached detailed Office action for a list of the certified copies not received. 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). Attachment(s) 15) Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s). 16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152) 20) Other: 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s).

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#### DETAILED ACTION

## Continued Prosecution Application

1. The request filed on 26 December 2001 (Paper No. 19) for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/103,355 is acceptable and a CPA has been established. An action on the CPA follows.

## Response to Amendment

- 2. Amendments filed 26 December 2001 (Paper No. 20) has been entered.
- 3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 4. Applicant's arguments filed 26 December 2001 (Paper No. 20), have been fully considered but they are not found persuasive.

## Claim Objections

5. Claim 6 is objected to because of the following informalities. Claim 6 has two periods at the end of the sentence. Appropriate correction is required.

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## Claim Rejections - 35 USC § 112, second paragraph

6. Claims 1- are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recite the term "nuclear transcription factor ligand" whose metes and bounds are not clear. The specification on page 6, line 1, define "nuclear transcription factor ligand" as a compound that binds to a nuclear transcription factor. specification on page 5, line 30, define "nuclear transcription factor" as referring to members of the nuclear transcription factor superfamily. Neither the claims nor the specification provides any structural or functional limitation which limits the metes and bounds of the term. This is especially confusing in light of applicants' response filed 26 December 2001 (Paper No. 20) on page 3 under "initial comments" because applicants argue that fos and jun are not regarded as receptors for a nuclear transcription factor ligand. It is not clear given the definition on pages 5 and 6 why fos and jun would not be encompassed by the recited term "nuclear transcription factor ligand." Applicants argue that examiner interpretation of the terms is at variance with the common usage in the art. However, as defined on pages 5-6 of the specification, it is not clear how

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the terms are being used by examiner in variance with common usage in the art since the specification help define the claim limitations.

Claim 1 recite the term "cognate receptor" whose metes and bounds are not clear. The specification on page 6, line 13, define "cognate receptor" as a receptor of the type that is typically bound by the transcription ligand in question. Neither the claims nor the specification provides any structural or functional limitation which limits the metes and bounds of the This is especially confusing in light of applicants' response filed 26 December 2001 (Paper No. 20) on page 3 under "initial comments" because applicants argue that fos and jun are not regarded as receptors for a nuclear transcription factor ligand. It is not clear given the definition on pages 5 and 6 why fos and jun would not be encompassed by the recited term "cognate receptor." Applicants argue that examiner interpretation of the terms is at variance with the common usage in the art. However, as defined on pages 5-6 of the specification, it is not clear how the terms are being used by examiner in variance with common usage in the art since the specification help define the claim limitations.

Claim 11 recite "said fos or said jun is c-jun" which is confusing and ambiguous because it is not clear how fos is c-jun.

Claims 12-13 recite the limitation "said nuclear

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transcription factor". There is insufficient antecedent basis for this limitation in the claim.

### Claim Rejections - 35 USC § 112, first paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 11 recite that fos is c-jun which is new matter not disclosed in the specification.

9. Claims 1-5 and 8-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

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application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 1-5 and 8-11 encompass cognate receptor whose structure cannot be envisioned by one of skilled in the art. The specification on page 6, line 13, define "cognate receptor" as a receptor of the type that is typically bound by the transcription ligand in question which provides no limitation in structure nor function. University of California v. Eli Lilly and Co. (CAFC) 43 USPQ2d 1398 held that a generic claim to human or mammalian when only the rat protein sequence was disclosed did not have written description in the specification. Thus, the disclosure does not have written description for the genus of cognate receptors which is not limited by structure nor function. One skilled in the art cannot envision the genus of cognate receptors claimed which is not limited by structure and function.

10. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed methods with specific species of estrogen receptor and Markush group of cognate receptors in claim 7 which are functional, but does not reasonably provide enablement for the claimed method using cognate receptors or estrogen receptor or Markush group of cognate receptors in claim 7 which are not

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functional. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 1 encompasses non functional receptor because of the claim limitation drawn to "cognate receptors". Claims 1-5 and 8-11 encompass claim 1. However, the specification on page 6, line 13, define "cognate receptor" as a receptor of the type that is typically bound by the transcription ligand in question. Neither the claims nor the specification provides any structural or functional limitation which limits the metes and bounds of the term and encompasses orphan receptors whose ligand is not known. Furthermore, the term encompasses other transcriptional factors and nuclear receptor family members which does not interact with estrogen receptor pathway. The state of the art is such that one skilled in the art cannot use method with an orphan receptor whose ligand is not known nor with transcription factors which does not interact with estrogen receptor or AP-1 pathway. No working example is provided to use method with an orphan receptor whose ligand is not known nor with transcription factors which does not interact with estrogen receptor or AP-1 pathway. would require empirical experimentation to determine how to use method with an orphan receptor whose ligand is not known nor with transcription factors which does not interact with estrogen

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receptor or AP-1 pathway. Thus, cognate receptors encompass a genus with a large number of species which are not functional and cannot be used in the claimed method. In view of the extent and the unpredictability of the experimentation required to practice the invention as claimed, one skilled in the art could not make the invention without undue experimentation.

Claims 1-13 encompass nonfunctional estrogen receptor because of the claim limitation drawn to "estrogen receptor" by name only without further structural or functional limitations. However, the specification does not teach how to use an estrogen receptor which is not functional. The state of the art is such that one skilled in the art cannot use an estrogen receptor without a DNA binding domain with tamoxifen (Webb et al. (Molec. Endocrinol., 1995), page 448). No working example is provided to use the method with a nonfunctional estrogen receptor. It would require empirical experimentation to determine how to use method with a nonfunctional estrogen receptor. Thus, estrogen receptor encompasses a genus with a large number of species which are not functional and cannot be used in the claimed method. In view of the extent and the unpredictability of the experimentation required to practice the invention as claimed, one skilled in the art could not make the invention without undue experimentation.

Claims 1-13 encompass nonfunctional cognate receptor of the Markush group recited in claims 6 and 7 because of the claim

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limitation drawn to "qlucocorticoid receptor" or other receptors by name only without further structural or functional limitations. However, the specification does not teach how to use an glucocorticoid receptor which is not functional. state of the art is such that one skilled in the art cannot use an glucocorticoid receptor without a DNA binding domain with dexamethasone (Pfahl et al., columns 11-12). No working example is provided to use the method with a nonfunctional glucocorticoid It would require empirical experimentation to receptor. determine how to use method with a nonfunctional glucocorticoid receptor. Thus, glucocorticoid receptor encompasses a genus with a large number of species which are not functional and cannot be used in the claimed method. Furthermore, one skilled in the art cannot predict how other cognate receptors such as androgen receptor, progestin receptor, vitamin D receptor, retinoic acid receptor, mineralcorticoid receptor, or prostaglandin receptor would function with the AP-1 system because no working example has been provided in the specification. In view of the extent and the unpredictability of the experimentation required to practice the invention as claimed, one skilled in the art could not make the invention without undue experimentation.

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### Claim Rejections - 35 USC § 102

11. Claims 1-5, and 8-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Kushner et al.((AB); U.S. 5,723,291).

The teachings of Kushner et al. has been set forth in the previous office action.

Kushner et al. teach a method with a cell or cells which express the estrogen receptors, fos, jun, and AP-1 promoter fused to CAT gene ((columns 4-8, 10-12, and 17-20). The cells were contacted with estrogen which resulted in detection of the reporter CAT (column 10). The limitation of cognate receptor is generic and encompasses additional estrogen receptors or fos and jun proteins in the cell. Page 6, lines 1-2, defines nuclear transcription ligand as a compound that binds to a nuclear transcription factor thus both fos and jun are nuclear receptors and ligands because they are transcription factors and they bind to each other. The definition of "cognate receptor" in the specification on page 6, lines 13-14, does not further limit claim than the receptor in claims 2 and 3. Furthermore, different ligands were tested simultaneously in figures 10-12 which meets the limitations of the claimed ligand. The newly amended claim limitations for the negative control is taught by transfection with or without jun or fos at the same time or singly (columns 10 and 13). Furthermore, Kushner et al. teach a

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method using MDA453 cells (columns 5, 14 and 15) which express endogenous estrogen receptor by transfecting with estrogen receptor fusion protein (columns 13-15). The estrogen receptor fusion protein is not excluded by the term "cognate receptor" and the ligands are estrogens and antiestrogens. The assays are performed with and without hormones (columns 13-15). Both fos and jun are in the methods of the assays in order for the AP-1 sites to work and thus are in contact with the cells. The cells are co-transfected with both estrogen receptor and Jun/Fos (column 13). The jun in the cell is c-jun (column 10).

Applicants argue that in view of the recitation as discrete elements, fos and jun are neither a transcription factor ligand nor a receptor for a transcription factor ligand. However, cells express more than one molecule of fos or jun and the additional proteins meets and does not exclude the limitations of the generic term of a transcription factor ligand nor a receptor for a transcription factor ligand. Also the two different types of estrogen receptors meet the limitation of cognate receptor and estrogen receptor.

12. Claims 1-5 and 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by GAUB et al.((AV); Cell, 1990).

GAUB et al. teaching has been set forth in the previous office action.

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GAUB et al. teach a method using the cell comprising estrogen receptor, ovalbumin element which is target for transactivation by c-fos and c-jun linked to CAT reporter(page 1271 and figure 6). Cells are contacted with TPA or forskolin and the receptor (HEO) and fos and jun and reporter activity measured (page 1271 and figure 6). Page 6, lines 1-2, defines nuclear transcription ligand as a compound that binds to a nuclear transcription factor thus both fos and jun are nuclear receptors and ligands because they are transcription factors and they bind to each other. TPA and forskolin activates the cell thus are compounds which have AP-1 mediated estrogenic activity. Thus, claim 1 limitations are met. Claim 2 requires a second cell and figure 6 were performed with more than one cell in a cell culture which comprises the all the elements of the first cell which meet the limitations of claim 2. Claim 3 limitation is that the cells are the same which is met above. Claims 4 and 5 definition of "cognate receptor" in the specification on page 6, lines 13-14, does not further limit claim than the receptor in claims 2 and 3.

Applicants argue that in view of the recitation as discrete elements, fos and jun are neither a transcription factor ligand nor a receptor for a transcription factor ligand. However, cells express more than one molecule of fos or jun and the additional proteins meets and does not exclude the limitations of the

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generic term of a transcription factor ligand nor a receptor for a transcription factor ligand. The term "transcription factor ligand" as defined is a generic term and does not exclude fos and jun because fos and jun are transcription factors which bind and thus are receptors as well.

13. Claims 1-5 and 9-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Evans et al.((B); U.S. 5,639,592) with evidence from Kushner et al.((AB); U.S. 5,723,291).

Evans et al. teach the method using a cell (such as HeLa, CV-1, NIH-3T3 cells; column 8) comprising c-jun, fos (column 5), and nuclear receptors (such as glucocorticoid, retinoic acid, estrogen, androgen, progesterone, vitamin D3, mineralcorticoid receptors; columns 6, 8-16). The column 7 teaches the method using AP-1 proteins by exogenous expression. Furthermore, column 5 teaches the method using AP-1 proteins endogenously or by administering fos or jun. Column 6 teaches the method using the estrogen receptor. The pages 7-8 of the specification's definition of "AP-1 mediated estrogen activity" is generic to the teachings of Evans et al. and does not exclude the teachings of Evans et al. Kushner provide evidence that HeLa, CV-1, and NIH-3T3 cells inherently express estrogen receptor (column 12, Table I).

Applicants argue that as discussed in the previous rejection

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response in view of the recitation as discrete elements, fos and jun are neither a transcription factor ligand nor a receptor for a transcription factor ligand. However, as discussed above, cells express more than one molecule of fos or jun and the additional proteins meets and does not exclude the limitations of the generic term of a transcription factor ligand nor a receptor for a transcription factor ligand. The term "transcription factor ligand" as defined is a generic term and does not exclude fos and jun because fos and jun are transcription factors which bind and thus are receptors as well.

14. Claims 1-2, 4, 8, and 10-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Pfahl et al.((A); U.S. 6,004,748) with evidence from Kushner et al.((AB); U.S. 5,723,291).

Pfahl et al. teaching was set forth in the last office action.

Pfahl et al. teaches a method of detecting AP-1 interaction with cell containing estrogen receptors and as well as AP-1 promoter (columns 1-3 and 7-8). Columns 2 and 4 teaches the method using AP-1 proteins, cJun and cFos, by exogenous expression. Furthermore, column 2 teaches the method using AP-1 proteins endogenously expressing fos or jun. Column 2 teaches the method using the estrogen receptor. The pages 7-8 of the

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specification's definition of "AP-1 mediated estrogen activity" is generic to the teachings of Pfahl et al. and does not exclude the teachings of Pfahl et al. including effects of dexamethasone. Kushner provide evidence that HeLa, CV-1, and NIH-3T3 cells inherently express estrogen receptor (column 12, Table I).

Page 6, lines 1-2, defines nuclear transcription ligand as a compound that binds to a nuclear transcription factor thus both fos and jun are nuclear receptors and ligands because they are transcription factors and they bind to each other. The definition of "cognate receptor" in the specification on page 6, lines 13-14, does not further limit claim than the receptor in claims 2 and 3.

## Claim Rejections - 35 USC § 103

- 15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the

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inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kushner et al.((AB); U.S. 5,723,291) in view of Pfahl et al.((A); U.S. 6,004,748), Evans et al.((B); U.S. 5,639,592), GAUB et al.((AV); Cell, 1990), Webb et al.(CB) and Kushner et al.((AD); WO 95/06754).

The teachings of Kushner et al.((AB); U.S. 5,723,291) Pfahl et al.((A); U.S. 6,004,748), Evans et al.((B); U.S. 5,639,592), and GAUB et al.((AV); Cell, 1990) have been discussed above.

Webb et al.(CB) and Kushner et al.((AD); WO 95/06754) are cumulative reference with Kushner et al.((AB); U.S. 5,723,291) Pfahl et al.((A); U.S. 6,004,748), Evans et al.((B); U.S. 5,639,592), and GAUB et al.((AV); Cell, 1990).

Claims 6 and 7 recite specific Markush group of ligands and cognate receptors, respectively, which are not taught by Kushner et al.((AB); U.S. 5,723,291).

It would have been obvious to modify the method of Kushner et al.((AB); U.S. 5,723,291) by incorporating the teaching of Pfahl et al.((A); U.S. 6,004,748), Evans et al.((B); U.S. 5,639,592), and GAUB et al.((AV); Cell, 1990) and further use the glucocorticoid receptor, retinoic acid receptor, or other nuclear

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receptors. One of skilled in the art would have been motivated combine the teaching of the references because they are analogous references which teach nuclear receptors interaction with AP-1 site and AP-1 protein interaction. Further motivation is provided by Evans et al. who teach that understanding the mechanism of the regulatory effect of hormones, receptors, and AP-1 transcription factors are important to determine undesirable side effects especially as it relates to proto-oncogenic effects of cell growth and differentiation (columns 1 and 2). Evans et al. motivation is especially important in view of the regulatory interaction of estrogen signalling pathway with glucocorticoid, progestins, and androgens as taught by Gaub et al. (Pages 1267 and 1273). Further motivation is provided by Pfahl et al. who teach that methods of the invention can be used to identify and screen new ligand of nuclear receptor useful for treatment of cancer because the receptors (such as estrogen and glucocorticoid etc.) interaction with AP-1 (columns 1-3).

### Double Patenting

17. Claims 1-13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 5,723,291 in view of Pfahl et al.((A); U.S. 6,004,748), Evans et al.((B); U.S.

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5,639,592), GAUB et al.((AV); Cell, 1990), Webb et al.(CB) and Kushner et al.((AD); WO 95/06754). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The teachings of Pfahl et al.((A); U.S. 6,004,748), Evans et al.((B); U.S. 5,639,592), GAUB et al.((AV); Cell, 1990), Webb et al.(CB) and Kushner et al.((AD); WO 95/06754) are discussed above.

It would have been obvious at the time of the invention to modify the method of claims 1-27 of U.S. Patent No. 5,723,291 by incorporating the teaching of Pfahl et al.((A); U.S. 6,004,748), Evans et al. ((B); U.S. 5,639,592), and GAUB et al. ((AV); Cell,1990) and further use the glucocorticoid receptor, retinoic acid receptor, or other nuclear receptors. One of skilled in the art would have been motivated combine the teaching of the references because they are analogous references which teach nuclear receptors interaction with AP-1 site and AP-1 protein interaction with interests in understanding cancer cell growth regulation. Further motivation is provided by Evans et al. who teach that understanding the mechanism of the regulatory effect of hormones, receptors, and AP-1 transcription factors are important to determine undesirable side effects especially as it relates to proto-oncogenic effects of cell growth and differentiation (columns 1 and 2). Evans et al. motivation is especially

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important in view of the regulatory interaction of estrogen signalling pathway with glucocorticoid, progestins, and androgens as taught by Gaub et al. (Pages 1267 and 1273). Further motivation is provided by Pfahl et al. Wwho teach that methods of the invention can be used to identify and screen new ligand of nuclear receptor useful for treatment of cancer because the receptors (such as estrogen and glucocorticoid etc.) interaction with AP-1 (columns 1-3).

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Webb et al.(CB) and Kushner et al.((AD); WO 95/06754) are cumulative references with Kushner et al.((AB); U.S. 5,723,291), Pfahl et al.((A); U.S. 6,004,748), Evans et al.((B); U.S. 5,639,592), and GAUB et al.((AV); Cell, 1990).

- 19. No claims are allowed.
- 20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday through Friday from 8:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to

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(703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Hicharl D. Mr.
Michael Pak

Primary Patent Examiner

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